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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,885	10/19/2004	Martin Purpura	5942-83616	4212

22242 7590 10/23/2009

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,885	PURPURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-16,18-21 and 23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-16, 18-21 and 23-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/17/09 and 07/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and IDS filed on 06/17/09 and 07/29/09 is acknowledged.

Claims 1, 6, 9-10, 21, 26-27 and 34-37 have been amended.

Claims **12, 17 and 22** have been cancelled. New claims 38-44 have been added in this application.

Claims **1-11, 13-16, 18-21 and 23-44** are under prosecution.

The Double Patenting rejections made in the previous office action have been withdrawn in view of filing of Terminal disclaimer.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11, 13-16, 18-21 and 23-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, 34, 36-37 and 43-44 recite broad and narrow limitations such as hydrophobic materials and hydrophobic polymers which makes the claim indefinite. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 6, 34, 36-37 and 43-44 recite the broad recitation hydrophobic materials and the claims also recite hydrophobic polymers which is the narrower statement of the range/limitation.

It is not clear if the limitation within parenthesis is really the limitation in (un)modified carbohydrates and (un) modified proteins in claims 1, 6, 34, 36-37 and 43-44. The word stabilizing is not clear in claims 1, 6, 34, 36 and 43-44, stable in what sense? Claims recite polyphenols, trace elements and mineral substances which make the claim indefinite because metes and bounds of claims are not defined. Appropriate correction is required.

Response to Arguments

4. Applicant's arguments filed 07/29/09 have been fully considered but they are not persuasive.

Regarding the limitation of reciting stable, Applicants point to instant specification, top paragraph for stating that the instant matrix comprising phospholipids can be added to food composition which could previously not be added due to hydrolysis and oxidation and thus the resulting matrix provides stability. In response to applicants arguments, it is pointed out that the properties that applicant is referring to are not reflected in claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore without having any limitation of hydrolysis and oxidation, the word stable or stabilizing is ambiguous.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11, 15-16, 18, 21, 23, 29-31, 34, 36, 38-39, 41 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 9107888, presented in IDS.

The reference teaches a powder, containing lecithin (an acetone –insoluble phospholipids), capable of readily performing handling and blending with a food or a feed, The powder enables the addition of a large amount of the lecithin, thereby improving the texture, keeping quality and reducing the scorching and mold releasability in the food. The powder comprising lecithin is taught to be suitable as a material for the food and feed which is excellent in keeping the quality of food by adsorbing the hardly handleable lecithins which are a liquid or a pasty at normal temperatures due to high hygroscopicity. The powder with lecithin is combined with excipients to prevent the hygroscopicity (thus making the composition stable). Various excipients that are used are grain flour, a seed powder, a potato powder, starch, an oil cake, a rice bran, food manufacture's by-products, an animal refuse and a mineral powder with lecithins obtained from an animal and a plant, see abstract. The reference thus teaches stable product.

7. Claims 1-11, 15-16, 18, 21, 23, 29-31, 34, 36, 38-39, 41 and 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Friedman (US pg pub

2003/0021881).

Friedman discloses homogeneous solid matrix containing proteins and lecithin see abstract and examples. The reference teaches solid matrix of various shapes for administration of ingestible bioactive compounds, the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023]. The composition teaches lecithin (which is also known in the art as phosphatidyl choline), triglycerides (a hydrophobic material) and soybean (protein) , see page 2, paragraph [0092-0094] and 0078. The reference teaches silica in the composition, paragraph [0046], vitamins and tocopherol in paragraph [0197]. Example 9 discloses fatty alcohol and lipid. The reference teaches polysaccharides in the composition, see paragraph [0012]. The amount of soybean lecithin is 0.5 gm to 1 gm in examples 19 and 20 which is more than 5% in the examples. The reference teaches utilizing wet granulation method for processing and extruding through the screen having openings of 0.5mm to 2.5mm and spheronized in a spheronizer, see paragraph 005.

It is to be noted that instant specification describes that phospholipids are typically insoluble in acetone which is why they are also refereed to as acetone-insoluble phosphatides or substances on page 1, therefore prior arts lecithin which is a phospholipid reads on the claimed component. Since the prior art teaches the claimed components, one would expect the composition to be stable absent evidence to contrary.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-11, 14-16, 18, 20-21, 23-24, 26-32, 34-39, 41 and 44 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2, presented in IDS) by itself or in view of Friedman (US PG Pub. 2003/0021881).

Kiliaan et al. discloses a nutritional preparation suitable for the prevention and/or treatment of vascular disorders, comprising long chain polyunsaturated fatty acids; phospholipids, the phospholipids contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol. The composition contains compounds which are a factor in methionine metabolism, containing at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (mineral) see (abstract).

The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5). Triglyceride (a hydrophobic material) is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on

page 12, various diseases and symptoms that can be treated are cognitive degeneration (thus improving mental fitness) and improper functioning associated with kidneys, liver, stomach etc. Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18).

Kiliaan discloses a capsule containing phospholipids comprised of phosphatidyl serine and phosphatidylcholine (acetone insoluble phospholipids); the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids. The composition of Kiliaan is administered to treat vascular disorders. The reference teaches that the composition can be in the form of tablet, powder, bar cookie or capsule, see page 6, lines 1-5. since the prior art teaches tablet and powder formulation, one would expect the matrix to be stable because prior art essentially teaches the claimed components.

While Killian teaches nutritional preparation can be in a tablet and powder form, Kiliaan does not specifically teach the claimed particle size. Friedman as discussed above teaches a nutritional preparation comprising solid matrix with particle size from 0.5mm to 2.5 mm (500 micrometer to 2500 micrometer) and discloses that the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023].

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have prepared the nutritional preparation of Killian et al. comprising particle

size in the range of 500 micrometer to 2500 micrometer for better dissolution and oral availability motivated by the teachings of Freidman et. al.

Regarding the amounts of various components, it is the position of the Examiner that it would have been within the purview of skilled artisan to have optimized the amounts of various components to come to the optimum level by doing experimental manipulations.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claim 32 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US pg pub 2003/0021881) and further in view of Ponroy (USP 6,069,138).

The references taught above do not disclose Sphingomyelin in the nutritional preparation.

Ponroy teaches use of phospholipids in therapy and dietetic composition, see abstract. The reference teaches importance of a composition comprising various phospholipids such as phosphatidylserine, phosphatidylcholine, sphingomyelin and lysophospholipids in improving the quality of nighttime sleep, alertness during the day

as well as memory and learning skills, see column 3, lines 14-20 and examples in column 3 and 4.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to incorporate lysophospholipid or sphingomyelin in the nutritional preparation of Killian and Freidman for therapeutic benefits such as memory and learning capabilities associated with various phospholipids motivated by the teachings of Ponroy's reference.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 8, 19 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US PG Pub. 2003/0021881) as discussed above and further in view of JP 61078351, presented in IDS.

The teachings of Geiss do not include lecithin in the form of microcapsule. JP teaches microcapsules comprising lecithin and coated with gelatin wherein the lecithin is prevented from being oxidized and deteriorated. The particle size is from 10-2000 micrometer, see abstract.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to include microcapsules comprising lecithin in the teachings of Killiaan in

order to have stabilized product because JP teaches that such preparation helps in preventing deterioration and oxidation of the product. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US pg pub 2003/0021881) in view of Vegetable Lecithins, Dr. Hermann Pardun (Verlag fLir chemische Industrie H. Ziolkowsky KG Augsbur, 1988, ISBN 3 87846 128 3), reference being presented in IDS.

The teachings of Freidman have been discussed above. The reference does not specifically teach cholesterol reduction, hyperlipidemia and dysfunctions of learning aptitude and the retentivity due to lecithin.

JP teaches lecithin helps in improving learning aptitude and treatment of hyperlipidemia due to lecithin, see the whole article. It would have been obvious too one of ordinary skill in the art at the time the invention was made to treat conditions such as hyperlipidemia and learning disabilities by providing the food product of Freidman which comprises lecithin.

13. Claims 14, 33 and 40 are rejected under 35 U.S.C. 103 (a) as being

unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US PG Pub. 2003/0021881) as discussed above and further in view of Geiss et al. (US PG pub.2004/0120985 A1).

The references taught above do not teach proteins such as whey proteins in the composition. Geiss teaches a composition comprising phosphatidyl serine and various excipients for improved cognitive performances, see examples. It would have been obvious to one of ordinary skill in the art at the time of instant invention to incorporate proteins in the composition of Killiaan because the reference teaches the composition effective for cognitive improvements.

CITED AS INTEREST

14. The following references have been cited as interest dealing with lecithin and preparation of solid matrix of different forms and treatment of various diseases with phospholipids.

EP 0072469. USP 5091187, USP 6103271 and USP6733797.

Response to Arguments

15. Applicant's arguments with respect to claims **1-11, 13-16, 18-21 and 23-44** have been considered but are moot in view of the new ground(s) of rejection.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612